24. (Previously presented) A compound that has been identified according to the method of claim 18.

REMARKS

I. Status of the Claims

Claims 11-24 are pending, have been examined, and stand rejected under 35 U.S.C. §112, first paragraph and 35 U.S.C. §112, second paragraph. The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

II. Rejection Under 35 U.S.C. §112, First Paragraph (Written Description)

A. Claims 18-24

Claims 18-24 stand rejected as allegedly lacking written description. The examiner continues to argue that "a critical element" of the invention is a binding partner for FKHL7. Thus, the alleged failure of the specification to identify any particular binding partners for FKHL7 is said to be problematic in that "the claims encompass an incredibly broad genus of compounds/molecules that must satisfy the functional limitation of being able to bind FKHL7." The examiner goes on to say that there is no basis in the application to "visualize" the characteristics of a sufficient number of binding partners to support "the broadly claimed genus of such binding partners." Finally, the examiner argues that even if ***certain*** binding partners were conceded, they would not support claiming of "specific binding partners of other types (*e.g.* small molecule agonists or antagonists)." Applicants respectfully traverse.

The examiner's rejection is premised on a number of different points, each of which applicants dispute. First, the examiner argues that neither the specification or the prior art provides ***any*** binding partner for FKHL7. As shown in Pierrou *et al.* (1994), the binding domain

of FKHL7 was actually identified in 1994, its ability to bind DNA was demonstrated, and its DNA binding specificity determined (see FIG. 3D, page 5005). Thus, DNA binding is more than a "mere possibility," and applicants submit that one of the "critical" facts upon which the rejection is based is invalid.

Second, and perhaps more fundamentally, the examiner seems to be confusing the requirement for written description for the binding partner of FKHL7 and the requirement for written description for the test compounds, which might bind FKHL7. In fact, these issues are quite distinct. One of skill in the art need not know anything about the structure of FKHL7 or its cognate target in order to envision a wide range of test compounds that could be tested for their ability to interfere with FKHL7 DNA binding. A perfect example is a small molecule library – one can easily "describe" an assay relying on such libraries, yet not know anything about the structures of such compounds (which are often proprietary). Put another way, the absence information about agonists and antagonists of FKHL7 does not raise issues of description for the simple reason that ***the basis of the claims is to identify such compounds, whatever their structural nature***. As such, it could not possibly to describe unidentified compounds in the present specification at the time of filing, and if they were identified, there would be no need to claim the screening assay, as opposed to the compounds themselves.

Third, the examiner acknowledges another type of FKHL7 binding partner – an antibody – but argues that one could not "envision the specific primary sequence of the antibody." Regardless of its veracity, this comment is irrelevant from the standpoint of written description. That this ***must*** be the case can be discerned immediately from searching the term "antibody" in issued U.S. patent claims. There are hundreds (if not thousands) of examples where an antibody to a novel protein is claimed, yet there is no "primary sequence" of the antibody provided in the

application, nor is a deposit of the antibody to be found. While each application clearly is judged on its own merits, the fact situation presented by such patents is even ***more*** rigorous with respect to written description than here as (a) the binding domain of FKHL7 was known in the prior art and (b) the antibody is not claimed *per se*, but is simply a possible element in a method claim. Thus, simply put, this is a non-issue with respect to the instant claims.

Finally, it must be reiterated that the provision of an FKHL7 binding partner – ***any*** FKHL7 binding partner – will permit one to screen ***all*** types of test compounds. Thus, even if the application describes only limited numbers of binding partners, this has no effect on the ability of the skilled artisan to practice the claimed invention, and thus no effect on their ability to envision an infinite number and type of test compounds. As anyone in the field of drug screening immediately recognizes, there is virtually ***no*** limitation on the possible ***target compounds***, and the present application clearly describes a wide range of such compounds.

Thus, for all of the foregoing reasons, applicants respectfully submit that the present specification provides more than adequate written description for the claimed invention. Reconsderation and withdrawal of the rejection is therefore respectfully requested.

B. Claims 14 and 24

The examiner also objects to the claims 14 and 24 as the specification allegedly describes no such compounds, much less fails to disclose any particular structures for such compounds. Applicants traverse. Claims 14 and 24 are "product-by-process" claims. Such claims are specifically contemplated where it is difficult or impossible to define products by their physical characteristics, *i.e.*, their structure. *In re Steppan et al.*, 156 USPQ 143 (CCPA 1967); *Ex parte Brian et al.*, 118 USPQ 242 (BPAI 1958). Product claims may include process steps that either

partially or wholly define the claimed product. *In re Hallman*, 210 USPQ 609 (CCPA 1981).

The examiner's only response to this line of argument is to repeat that the specification (a) does not describe such compounds, and (b) that no "structures" can be "envisioned" based on the described methods from which these claims depend. However, this explanation is no explanation at all, since this argument could be made ***about most product-by-process claims***. As stated above, such claims are appropriate where defining the product by reference to structural features is difficult or impossible. To argue, then, that the absence of structure is relevant to the ***written description*** of such compounds is, simply put, non-sensical. Thus, applicants reiterate that the rejection – which relies on no case law that deals specifically with product-by-process claims – is improper. Applicants again respectfully request reconsideration and withdrawal of the rejection.

III. Rejection Under 35 U.S.C. §112, First Paragraph (Enablement)

Claims 11-24 stand rejected for alleged lack of enablement in light of a thorough analysis by the examiner using the *Wands* factors.[1] In coming to a conclusion of non-enablement, the examiner relies heavily on the following: (a) the perceived breadth of the claims with respect to binding partners and biological activities for FKHL7; (b) the absence of evidence for DNA binding, generally or with regard to a specific DNA sequence; (c) the unpredictability in the art with regard to the existence of binding partners for FKHL7 based on protein structure alone; and (d) the amount of experimentation needed to determine if FKHL7 is in fact a transcription factor. Because most of these determinations are incorrect, applicants respectfully traverse the rejection.

[1] The skill of those in the art is not mentioned, but presumably the examiner will agree with applicants that the skill is high.

As discussed above, the prior art provides far more information regarding the biological activity than the examiner has realized. Pierrou *et al.* (1994) clearly describe the binding domain of FKHL7, as well as its ability to bind DNA. Most significantly, the DNA binding specificity of FKHL7 was determined in that report (see FIG. 3D, page 5005). This observation alone severely undermines the examiner's position, as a great deal of the rejection is based upon the perceived ***absence*** of such information. With this matter clarified, applicants submit that the balance of (i) guidance, (ii) state of the art, (iii) predictability in the art, and (iv) amount of experimentation necessary shift in favor of applicants, and argue in favor of enablement.

An additional comment on the examiner's concerns regarding amount of experimentation is merited. The examiner notes applicants' previous submission relating to "global" transcription and binding assays, but poses many questions regarding conditions for such assays and whether they would be sensitive enough to identify specific modulators of FKHL7 bioactivity. However, one of skill in the art is well aware of the methods that would permit such assays to be performed with ease. For example, one could use purified FKHL7 in an *in vitro* transcription reaction where other transcription factors have been omitted, thereby eliminating concerns for spurious transcriptional activity. Even simpler would be the use of a DNA binding assay (*e.g.*, band shift) using purified genomic DNA, or oligos having the FKHL7 binding site as defined by Pierrou *et al.* Thus, the difficulties alleged by the examiner trivial to those of skill in the art and would not provide meaningful obstacles to the practicing of the present invention.

In sum, when taking in to account the facts as set forth above, applicants respectfully submit that the claims are indeed enabled by the instant specification. Reconsideration and withdrawal of the rejection is, therefore, respectfully requested.

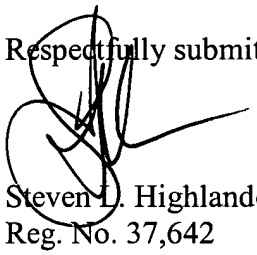
IV. Rejection Under 35 U.S.C. §112, Second Paragraph

The examiner has rejected claims 18-24 as allegedly indefinite. Applicants have provided the suggested amendment to claim 18, which is believed to address of the rejection. Reconsideration and withdrawal of the rejections is therefore respectfully requested.

V. Summary

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early indication to that effect is earnestly solicited. The examiner is invited to contact the undersigned at (512) 536-3184 with any questions, comments or suggestions relating to the referenced patent application. Please date stamp and return the enclosed postcard as evidence of receipt.

Respectfully submitted,



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